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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,437

11/30/2004

Scott Manzo

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7590

11/05/2010

EXAMINER

EASTWOOD, DAVID C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

11/05/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,437	<b>Applicant(s)</b> MANZO, SCOTT	
	<b>Examiner</b> David Eastwood	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/19/2010 has been entered.

### ***Response to Amendment***

Receipt is acknowledged of applicant's amendment filed 7/19/2010. Claim 9 has been cancelled without prejudice. Claims 1-8 and 10-27 are pending and an action on the merits is as follows.

Applicant's arguments with respect to the newly presented limitations in the amended claims have been fully considered and are addressed by a new ground(s) of rejection as set forth below.

### ***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 22-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Vargas et al. (US 6537288) (hereafter Vargas).

Regarding claims 22-27, Vargas discloses an anchoring assembly (800) for use in a surgical anastomosis procedure, comprising a flange member (802) having a head

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portion (portion of 802 extending beyond the expandable frame portion as depicted in figure 30) and an expandable annular body (note expansion of analogous structure 120 as depicted in figures 5-8 and discussed in C9 L10-17) integrally coupled to the head portion (fig. 30), the head portion protruding laterally from the expandable annular body (note figure 31) and defining proximal and distal end surfaces (note figure 31), the proximal end surface including a plurality of protuberances (806) formed thereon and extending proximally therefrom (note figure 31 and C19 L40-47), the flange member defining a passage extending through the head portion and the annular body (fig. 31) and a locking member (156) discrete and separable from the flange member (note figure 5 regarding the locking member illustrated in use with structure 120 analogous to device depicted in figures 30 and 31), the locking member defining a lumen there through (fig. 5), the locking member being configured and adapted to radially deflect the expandable annular body upon maintained engagement of the locking member within the passage of the annular body such that the locking member is secured within the passage of the annular body (note progression of figures 5-8 with respect to the analogous structure and C9 L19-23), the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots (slots between elements 826 note figure fig. 32 depicting analogous structure 820) formed therein, wherein the annular body is expandable along the pair of longitudinal slots (Note figure 31 and C9 L10-17 with respect to the analogous structure 120), the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded (C9 L10-17 and note depiction of analogous

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structure depicted in fig. 5-8 and C19 L30-34 with respect to the analogous structure statements), the head portion of the flange member has a radius which is larger than the first radius of the annular body (fig. 31), the locking member comprises a cylindrical body having a distal end portion (fig. 5), wherein the cylindrical body has a radius which is larger than the first radius of the annular body (note relative diameters of the claimed elements as depicted in fig. 5 with respect to the structure analogous to element 800 and C9 L10-17) and wherein the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body (note figure 5), the longitudinal slots extend through a proximal end of the annular body and terminate at a distance spaced from the head portion (fig. 30 and 32).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3-8, 10-11 and 13-15, are rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas et al. (US 6537288) (hereafter Vargas) in view of Ginn et al. (US 6695867) (hereafter Ginn).

Regarding claim 1, Vargas discloses an apparatus for performing a surgical anastomosis comprising, a tubular sleeve (152) defining an axial lumen there through (fig. 5), a positioning tube (154) defining an axial lumen there through (fig. 5), the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve (fig. 5-8) and an anchoring assembly (800) including, a flange member (note element 134 of analogous element depicted in figure 5-8 further note C19 L30-34 with respect to the analogous structure statements) having an expandable annular body (annular body of element 800 see C9 L10-17 and note depiction of analogous structure depicted in fig. 5-8 and C19 L30-34 with respect to the analogous structure statements) a head portion (802) integrally coupled to the expandable annular body (note figure 30 and 31) and protruding laterally therefrom (note figure 31), the annular body defining a passage (opening through element 800 depicted in figure 31), the passage extending through the head portion and the annular body (see figure 31), the head portion defining proximal and distal end surfaces (note figure 31), the proximal end surface including a plurality of protuberances (806) formed thereon and extending proximally therefrom (note figure 31 and C19 L40-47); and a locking member (156) configured and dimensioned to be received in the passage of the annular body (fig. 5-8), the locking member defining a lumen there through (fig. 5-8), wherein movement of the locking member into the passage of the annular body induces

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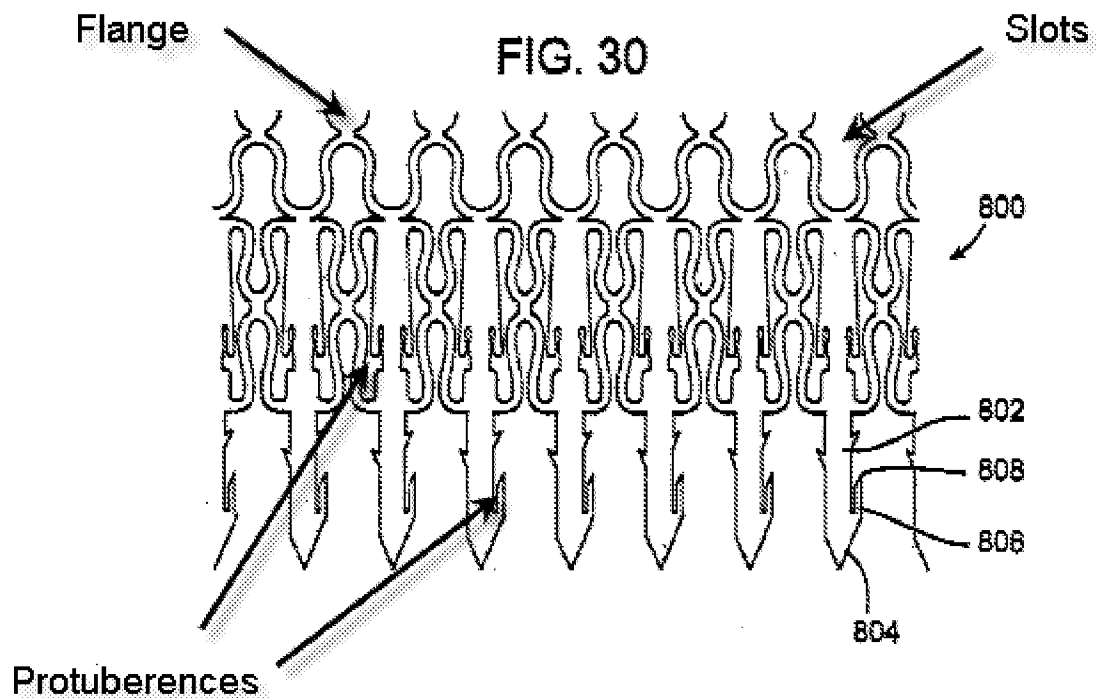
movement of the annular body of the flange member between an unexpanded configuration and a radially expanded configuration upon wherein the locking member is maintained in the annular body to maintain the annular body in the expanded configuration (C9 L10-17 and note depiction of analogous structure depicted in fig. 5-8 and C19 L30-34 with respect to the analogous structure statements).

Vargas fails to explicitly disclose an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube. However, Ginn discloses an expansion assembly (218 and description of element 18 from which 218 is derived note C15 L15-18 and 27-33) having a tubular body and an expandable tip (note fig. 5 a and b) operatively coupled to a distal end thereof (fig. 10), the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube (note figures 6c and 6d). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Vargas with the expandable member of Ginn. Doing so would provide assistance in positioning the device as taught by Ginn (C15 L14-18).

Regarding claims 3-6, Vargas discloses the annular body of the anchoring assembly comprises at least a pair of diametrically opposed longitudinal slots (slots between elements 826 note figure fig. 32 depicting analogous structure 820) formed

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therein, wherein the annular body is expandable along the pair of longitudinal slots (note figure 31 and description of expansion of the annular body as described with respect to claim 1), the annular body of the anchoring assembly includes a plurality of protuberances (see figure below) formed on an outer surface thereof, the annular body of the anchoring assembly has a first radius when not expanded and a second radius, larger than the first radius, when expanded (see fig. 5-8 with respect to the analogous structure and figure 31), the head portion (noted above) of the flange member has a radius which is larger than the first radius of the annular body (note position of and size of head portion relative to the flange member as depicted in fig. 31)





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Regarding claim 7, Vargas and Ginn disclose the locking member (156 of Vargas) comprises a cylindrical body having a distal end portion (fig. 5), wherein the cylindrical body has a radius which is larger than the first radius of the annular body (fig. 5 as depicted relative to the analogous structure of device 800), the distal end portion of the cylindrical body tapers down to a radius which is smaller than the first radius of the annular body (note figure 6 regarding relative size between element 156 and the analogous structure to element 800).

Regarding claim 8, 10-11, Vargas discloses the longitudinal slots extend through a proximal terminal end of the annular body and terminate at a distance spaced from the head portion (note figure 5 and 6 with respect to the analogous structure), the head portion includes a tapered distal surface (note tapering of head portion from the proximal end to the distal end depicted in figure 30 and 31), the annular body of the anchoring assembly comprises a plurality of longitudinal slots formed therein (note plurality of slots depicted in fig. 30).

Regarding claim 13, Vargas discloses a proximal end of the locking member is configured and adapted to engage a distal end of the positioning tube (note position of locking member relative to the positioning tube in fig. 7 and 8 where the distal end of the locking member is beyond the distal end of the positioning tube therefore the locking member is configured and adapted to engage a distal end of the positioning tube), the head portion of the flange member has a radius which is larger than a radius of the lumen of the tubular sleeve (fig. 5-8 with regard to the claimed elements and the structure of element 120 analogous to device 800), the head portion of the flange

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member has a radius which is smaller than an inner radius of the lumen of the tubular sleeve (fig. 5-8).

4. Claim 2 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas et al. (US 6537288) in view of Ginn et al. (US 6695867) further in view of Yencho et al. (US 6206913) (hereafter Yencho).

Regarding claim 2, Vargas and Ginn disclosed the claimed invention except for the expandable tip of the expansion assembly is a balloon. However, Yencho discloses a balloon expandable tip (151). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Vargas and Ginn with the balloon of Yencho in order to provide an expandable member the results of the substitution would have been predictable.

Regarding claim 12, Vargas and Ginn as modified by Yencho discloses an apparatus as stated above wherein the annular body of the anchoring assembly comprises at least one helical slot (where "helical" is taken to mean "having a shape approximating that of a helix") extending through (figure 24 (Yencho), where "through" is taken to mean "up to and including") the terminal end of the annular body.

5. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas et al. (US 6537288) (hereafter Vargas) in view of Ginn et al. (US 6695867) (hereafter Ginn) further in view of Weadock (US 6629988).

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Regarding claim 16, Vargas and Ginn disclose the claimed invention except for the anchoring assembly is made from a bio-absorbable material. However, Weadock teaches an anchoring assembly made from bioabsorbable material (12 see C4 L43-47).

It would be obvious to one of ordinary skill in the art at the time of the invention to have the anchoring assembly be made from bioabsorbable material as taught by Weadock, since Weadock states that making the assembly with bioabsorbable material allows the assembly to be resorbed as the anastomosis heals (column 2, lines 43-60).

6. Claims 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vargas et al. (US 6537288) (hereafter Vargas) in view of Ginn et al. (US 6695867) (hereafter Ginn) as applied to claims 1, 3-8, 10-11 and 13-15 above further in view of Edelstein (US 5591179).

Regarding claim 17, Vargas and Ginn as applied to claims to claims 1, 3-8, 10-11 and 13-15 above disclose a method for performing a surgical anastomosis, comprising the steps of providing an apparatus for performing the surgical anastomosis, the apparatus comprising (see rejection of claims 1, 3-8, 10-11 and 13-15 above), a tubular sleeve defining an axial lumen there through, a positioning tube defining an axial lumen there through, the positioning tube being configured and adapted to be slidably received within the axial lumen of the tubular sleeve, an expansion assembly having a tubular body and an expandable tip operatively coupled to a distal end thereof, the expandable tip having a retracted position in which the expandable tip can pass through the axial lumen of the positioning tube and an expanded position in which the expandable tip can not pass through the axial lumen of the positioning tube and an anchoring assembly

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including a flange member having an expandable annular body and a head portion integrally coupled to the expandable annular body and protruding laterally therefrom, the annular body defining a passage extending through the head portion and the annular body, The head portion defining proximal and distal end surfaces, the proximal end surface including a plurality of protuberances formed thereon and extending proximally therefrom; and a locking member arranged to be received in the passage of the flange member, the locking member defining a lumen there through, the locking member being configured and adapted to radially deflect the expandable annular body upon insertion of the locking member within the passage of the annular body and to maintain the expandable annular body in the radially deflected configuration when the locking member is received in the passage of the flange member (see rejection of claims 1, 3-8, 10-11 and 13-15 above), passing the apparatus through an opening in a body vessel such that the head portion of the flange member of the anchoring assembly is positioned within the body vessel (note position of head portion within skin 32 within newly formed body vessel as depicted in figures 7-8 with respect to the analogous structure 120 and as depicted in figure 31 with respect to device 800), advancing the positioning tube (154) through the tubular body (152) to drive and secure the discrete locking member (156) of the anchoring assembly into the annular body of the flange member (as disclosed above) and to deflect the annular body radially outward against the inner surface of the body lumen (note fig. 31 and progression of fig. 5-8 with respect to the analogous structure 120) ,

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Vargas fails to disclose advancing the expansion assembly through the positioning tube such that the expandable tip is within the body vessel, expanding the expandable tip within the body vessel withdrawing the tubular body of the expansion assembly to press the protuberances formed on the proximal end surface of the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen.

However Ginn discloses advancing the expansion assembly through a positioning tube such that the expandable tip is within the body vessel (Ginn Fig. 6c-6d), expanding the expandable tip within the body vessel (Gin Fig. 10) withdrawing the tubular body of the expansion assembly to press the head portion of the flange member of the anchoring assembly against the body vessel and to approximate the body vessel with the body lumen until the annular body of the flange member of the anchoring assembly is positioned within a distal end of the body lumen (Ginn C19 L19-35). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Vargas with the teachings of Ginn providing an additional means for securing the proximal protuberances within the target tissue. Vargas and Ginn both disclose methods for performing an anastomosis on a body vessel therefore the combination of the teaching of Vargas with the teachings of Ginn would yield predictable results.

Vargas and Ginn fail to explicitly disclose passing the apparatus through a body lumen. However, Edelstein discloses passing an anastomosis device through a body

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lumen (C3 L15-30). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Vargas and Ginn with the method step as disclosed by Edelstein. Vargas and Ginn disclose a method of performing an anastomosis as does Edelstein therefore the combination of the teaching of Vargas and Ginn with the teachings of Edelstein would yield predictable results.

Regarding claim 18-19, Vargas and Ginn disclose the step of retracting the expandable tip of the expansion assembly (C14 L33-40 Ginn), withdrawing the tubular body, the positioning tube and the expansion assembly from the body lumen (C14 L56-65).

Regarding claims 20-21, Vargas, Ginn and Edelstein disclose the surgical anastomosis is a radical prostatectomy (C4 L51-62), the radical prostatectomy includes the steps of removing the prostate gland from between the urethra and the bladder to define a urethral stump and a bladder neck (C4 L51-62 and fig. 2 and 8).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Eastwood whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. E./  
Examiner, Art Unit 3731  
10/30/2010

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
11/04/10